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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,738	11/08/2001	Robert H. Lustig	20609/191 (UTRC 00035)	2613

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,738	LUSTIG, ROBERT H.	
	Examin r	Art Unit	
	Maury Audet	1654	

-- Th MAILING DATE of this communication appears on the c ver sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 20, it is unclear what is meant by the phrase "reducing the caloric intake in an obese patient"? It is unclear how the administration of a compound can reduce the caloric intake of anyone, let alone an obese patient, since a person who is still hungry may maintain the same caloric intake regardless of agent administered or even force-feed him/herself even if not hungry. It was also not found in the specification where such a result can be guaranteed. Agents are known to be able to suppress appetite, but no known agent has the capability of reducing caloric intake. It is suggested that Applicant replace the phrase "reducing the caloric intake" with a phrase such as "appetite suppression".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claimed invention is drawn to three related methods of treating an adult patient exhibiting primary insulin hypersecretion (i.e. treating obesity (claims 1-10); reducing the caloric intake (claims 11-20); and inhibiting insulin hypersecretion (by pancreatic β-cells) (claims 21-30)) using somatostatin or related compounds to treat adult patients (i.e. human, claims 10, 20, 30); comprising administering somatostatin or related compounds intramuscularly (claims, 2, 12, 22); in an effective amount of about 20-50 mg/month (claims 3, 13, 23); subcutaneously (claims 4, 14, 24); in an effective amount of about 1-100 μg/kg per day (claims 5, 15, 25); using a somatostatin agonist (claims 6, 16, 26) such as an analog (claims 7, 17, 27), for instance octreotide or lanreotide (claims 8, 18, 28) or an agonist of somatostatin receptor type 2 or 5 (claims 9, 19, 29).

Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Coy et al. (US 4853371).

Coy et al. teach the use of somatostatin and analogs (col. 1, line 14-23), by intramuscular (IM) [parenteral] or subcutaneous (SC) delivery (claim 10), "administered to a mammal, e.g., a human, in a dosage of 0.01 to 50 mg/kg/day, preferably 0.1 to 5 mg/kg/day" (col. 4, lines 33-35); to reduce insulin secretion (claim 3) (see also claims 1-11).

Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/51331 (Societe de Conseils de Recherches Et D' Applications Scientifiques S.A.; Cawthorne et al.).

WO 98/51331 teach the use of somatostatin and analogs, by intramuscular (IM) [parenteral] or subcutaneous (SC) delivery, to a human, at a dosage between 5μg/day to 5

mg/day or a therapeutically effective amount thereof as decided by the physician; in a method for weight reduction for an obese patient (all taught on p. 3)(wherein intrinsic that administration of somatostatin for obese patient acts via insulin reduction).

Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lotter et al. (Journal of Comparative and Phvsiological Psvchology. 95:278-287 (1981)).

Lotter et al. teach the use of somatostmin to decrease food intake in mammals.

Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Levine et al. (Pharmacology Biochemistry & Behavior. 16:897-902 (1982)).

Levine et al. teach peripherally administered somatostatin for the reduction of feeding in mammals.

Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lustig et al. I (The Journal of Pediatrics. 135:162-1 68 (August 1999)).

Lustig et al. I teach the use of somatostatin agonists for obesity, and reversal of such mechanisms as altered glucose and insulin dynamics.

Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lustig et al. II (Endocrinology/Diabetes Pediatric Research Program Issue APS-SPR. New Orleans, LA, 43(4), Abstract No. 455 (April 1998)).

Lustig et al. II teach the use of the somatostatin analog octreotide to reverse obesity resulting from insulin hypersecretion.

Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lustig (Society for Neuroscience. 23. Society for Neuroscience Annual Meeting. New Orleans, LA, Abstract No. 102.34 (October 1997)).

Lustig teaches the use of somatostmin to decrease food intake in mammals.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coy et al. (US 4853371), in view of any of the following six references:

WO 98/51331 (Societe de Conseils de Recherches Et D' Applications Scientifiques S.A.; Cawthorne et al.);
Lotter et al. (Journal of Comparative and Phvsiological Psvchology. 95:278-287 (1981));
Levine et al. (Pharmacology Biochemistry & Behavior. 16:897-902 (1982));
Lustig et al. I (The Journal of Pediatrics. 135:162-1 68 (August 1999)) ;
Lustig et al. II (Endocrinology/Diabetes Pediatric Research Program Issue APS-SPR. New Orleans, LA, 43(4), Abstract No. 455 (April 1998)); or
Lustig (Society for Neuroscience. 23. Society for Neuroscience Annual Meeting. (New Orleans, LA, Abstract No. 102.34 (October 1997));

The seven references are all discussed above.

Coy et al., as discussed above, although expressly teaches the use of somatostatin and analogs to reduce insulin secretion (the underlying mechanism for inducing weight loss in obese adults), does not expressly state use of somatostatin to reduce weight (i.e. in obesity).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use, if not intrinsic thereto, the somatostatin or analog for reducing insulin secretion in a method for weight reduction in obesity adults in Coy et al., because the other six references (WO 98/51331; Lotter et al.; Levine et al.; Lustig et al. I; Lustig et al. II, and Lustig) all teach the advantageous use of somatostatin for obesity/weight reduction and because Coy et al. teach that the composition may be administered to "a patient in need of said compound" [somatostatin or analogs] (see i.e. claim 11), of which obesity/weight reduction is taught by the references as "a need" thereof". Furthermore, administration of somatostatin to reduce insulin secretion naturally triggers the weight loss for an obese adult (and hence has been carry out such) based on the underlying biochemical processes triggered in the somatostatin-insulin interaction.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the following five references:

Lotter et al. (Journal of Comparative and Phvsiological Psvchology. 95:278-287 (1981));
Levine et al. (Pharmacology Biochemistry & Behavior. 16:897-902 (1982));
Lustig et al. I (The Journal of Pediatrics. 135:162-1 68 (August 1999)) ;
Lustig et al. II (Endocrinology/Diabetes Pediatric Research Program Issue APS-SPR. New Orleans, I.A, 43(4), Abstract No. 455 (April 1998)); or
Lustig (Society for Neuroscience. 23. Society for Neuroscience Annual Meeting. (New Orleans, LA, Abstract No. 102.34 (October 1997));

in view of either Coy et al. or WO 98/51331 (Societe de Conseils de Recherches Et D' Applications Scientifiques S.A.; Cawthorne et al.).

The seven references are all discussed above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use, if not intrinsic thereto, to use any somatostatin or analog, by IM or SC delivery, in an effective amount of 20-60 mg/month or 1-100 μg/kg per day, respectively, in the somatostatin for treatment of obesity by insulin reduction teachings of any of Coy et al.; Lotter et al.; Levine et al.; Lustig et al. I; Lustig et al. II, and Lustig; because Coy et al. (col. 4, lines 33-35) and WO 98/51331 (p. 3) teach the advantageous use of somatostatin and analogs by the delivery routes and therapeutically effects amounts claimed by Applicant and because each of the references teach the somatostatin for treatment of obesity by insulin reduction

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA
September 30, 2003

CHRISTOPHER R. TATE
PRIMARY EXAMINER